



ORION-3

Long-Term Extension Study of ORION-1 ([NCT03060577](https://clinicaltrials.gov/ct2/show/study/NCT03060577))



ONGOING
Phase 2 Study

ORION-3 is an ongoing, open-label, non-randomized, extension trial of ORION-1. Participants enrolled into ORION-3 in two groups. Group 1 will assess the efficacy, safety and tolerability of long-term dosing of inclisiran sodium 300 mg. Group 2 will assess switching from 140 mg of evolocumab after one year to three years of treatment with inclisiran sodium 300 mg. The primary endpoint is percentage change in LDL cholesterol (LDL-C) from baseline in ORION-1 to day 210 (seven months) in ORION-3 for subjects in Group 1.



PATIENT POPULATION

Participants with atherosclerotic cardiovascular disease (ASCVD) or ASCVD-risk equivalents (e.g., diabetes and familial hypercholesterolemia) and elevated LDL-C who completed ORION-1 and met all inclusion and exclusion criteria enrolled into ORION-3 in two groups.



LOCATIONS

52 sites in five countries



STUDY TIMEFRAME

March 2017 – 2022



METHODOLOGY

In Group 1 (n=290), subjects previously treated with any inclisiran sodium dose in ORION-1 received twice-a-year injections of inclisiran sodium 300 mg. The primary endpoint is mean percent change in LDL-C from the ORION-1 baseline value, measured at day 210 (seven months) in Group 1.



In Group 2 (n=92), subjects previously treated with placebo in ORION-1 received one year of treatment with evolocumab (140 mg injections every two weeks) followed by three years of treatment with inclisiran sodium 300 mg given on days 360 (12 months) and 450 (15 months), and every six months thereafter. Safety and efficacy of switching from evolocumab to inclisiran sodium will be assessed in an exploratory manner. Follow-up for Group 2 is ongoing, and completion is projected to occur in 2022.

Interim results from ORION-3 for Group 1 only were presented at the 2019 National Lipid Association (NLA) Scientific Sessions (Long-Term Twice-a-Year Dosing of Inclisiran, a Novel siRNA Therapy, Results in Persistent LDL-C Lowering in Phase 2 Extension Study: ORION-3). [Click here](#) to access news release with more information.

Inclisiran is an investigational drug not yet approved for use by the FDA or any other regulatory authority.

Updated August 2019.